

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

7953.4.999.13

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

OFFICE OF THE COMMISSIONER
OF PATENTS AND TRADEMARKS
WASHINGTON, D.C. 20231

REFERRED TO: P.S. - 7A
REC'D

JAN 26 1999

Pennie & Edmonds
D.C. for filing

EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

#13

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

Commissioner of Patents and Trademarks

FEB 08 1999

HOWREY & SIMON (M.P.)

RECEIVED
PENNIE & EDMONDS

JAN 27 1999

CA OFFICE

Docketed For

4/22/99

RS DUE
DOCKETED-VRS

4/22/99

7/22/99 F

Office Action Summary

Application No.
05/844336Applicant(s)
Contag et alExaminer
V. RYANGroup Art Unit
1641

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above claim(s) 10-15, 17-20 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9, 16 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3, 4, 3, 9 ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

Art Unit: 1641

DETAILED ACTION

The Group and/or Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

Election/Restriction

Applicant's election without traverse of Group I (claims 1-9, and 16) in Paper No. 7 is acknowledged.

This application contains claims 10-15, and 17-20 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

In this application:

Claims 1-20 are pending.

Claims 10-15, and 17-20 are withdrawn from consideration by the Examiner.

Claims 1-9, and 16 are under examination.

Art Unit: 1641

Drawings

The drawings are objected to under 37 CFR 1.84 or 1.152 for the reasons stated on PTO 948. Correction is required.

Claim Rejections - 35 USC § 112

Claims 1-9, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite as it depends from a non-elected claim.

Claim 1 recites the limitation "the" detection of a selected substance. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more

Art Unit: 1641

than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, and 16 are rejected under 35 U.S.C. 103 as being obvious by Karube et al in view of Sleight et al.

Karube et al (Current Opinion in Biotechnology 5(1):54-59, 1994) teach biosensor cells used for the detection and analysis of specific substrates. The biosensors are comprised of a microorganism sensing element which recognize specific

Art Unit: 1641

substrates, and a transducer to convert the biochemical signal produced into an electronic signal. (See especially page 54, first column)

Karube et al teach that the transducer can be a photodetector, potentiometric electrodes, amperometric electrodes and thermistors. (See especially page 54, second column)

The reference also discloses that the visible reaction observed can be luminescence by fusing the luxAB gene to the flxAB gene. (See especially page 56, first column)

Karube et al disclose biosensors, however, the reference differs in not teaching an extracellular ligand-specific moiety and an intracellular signal transforming domain.

Sleight et al (Sleight et al. Signal Transduction. In: Cell Physiology Source Book. N. Sperelankis (ed). 1995.) teach that a variety of substances act as extracellular signals by binding to specific receptors located on the cell surface. By a process known as signal transduction, the extracellular signal stimulates an intracellular change which leads to the formation or release of an intracellular signal. (See especially page 117)

Given the teachings of the prior art that cells convert extracellular signals to intracellular physiological responses and biosensors are comprised of immobilized cells, it would have

Art Unit: 1641

been obvious to one of ordinary skill in the art at the time the invention was made to produce a biosensor comprised of an extracellular ligand-specific moiety, and an intracellular signal transforming domain as the art teaches that bacterial cells use a process known as signal transduction to convert an external chemical signal created by the binding of a specific substrate to an intracellular signal to effect the function of a large number of proteins and the use of luciferase produces a light response which can easily be detected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette,

Art Unit: 1641

1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
January 1999
Ryan/vr


JAMES C. HOUSEL 1/19/99
5u ADVISORY PATENT EXAMINER